Cardiovascular Metallic Implants: Corrosion, Surface Characterization, and Nickel Leaching

March 8-9, 2012

FDA, Silver Spring, MD

Workshop Organizing Committee

Program Committee:

- Ashley Boam
- Ronald Brown
- Kenneth Cavanaugh
- Matthew Di Prima* (matthew.diprima@fda.hhs.gov)
- Rosalie Elespuru
- Jennifer Goode* (jennifer.goode@fda.hhs.gov)
- Nicole Ibrahim* (nicole.ibrahim@fda.hhs.gov)
- Srinidhi Nagaraja
- David Saylor* (david.saylor@fda.hhs.gov)
- Erica Takai* (erica.takai@fda.hhs.gov)
- Terry Woods

Logistics:

- Susan Monahan
- Nicole Ibrahim
- Lisa Lim
- Erica Takai

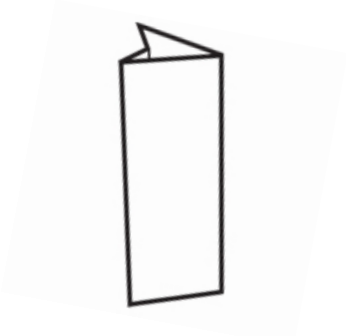
Special thanks to Dorothy Abel and Donna Lochner

*moderators

Workshop Logistics

Format:

- Limited presentations (sessions 1-3)
- Moderated discussion with lead discussants
  - Limited audience participation as time permits
  - Strict time limits for discussions



Ground Rules:

- Tent cards upright to comment
- State your name each time before you comment

Other:

- Box lunch, snacks, and coffee available for purchase
- Visitors can only access Building 31 (workshop site)

Workshop Agenda

Day 1:

- Corrosion
- Surface Characterization

Day 2:

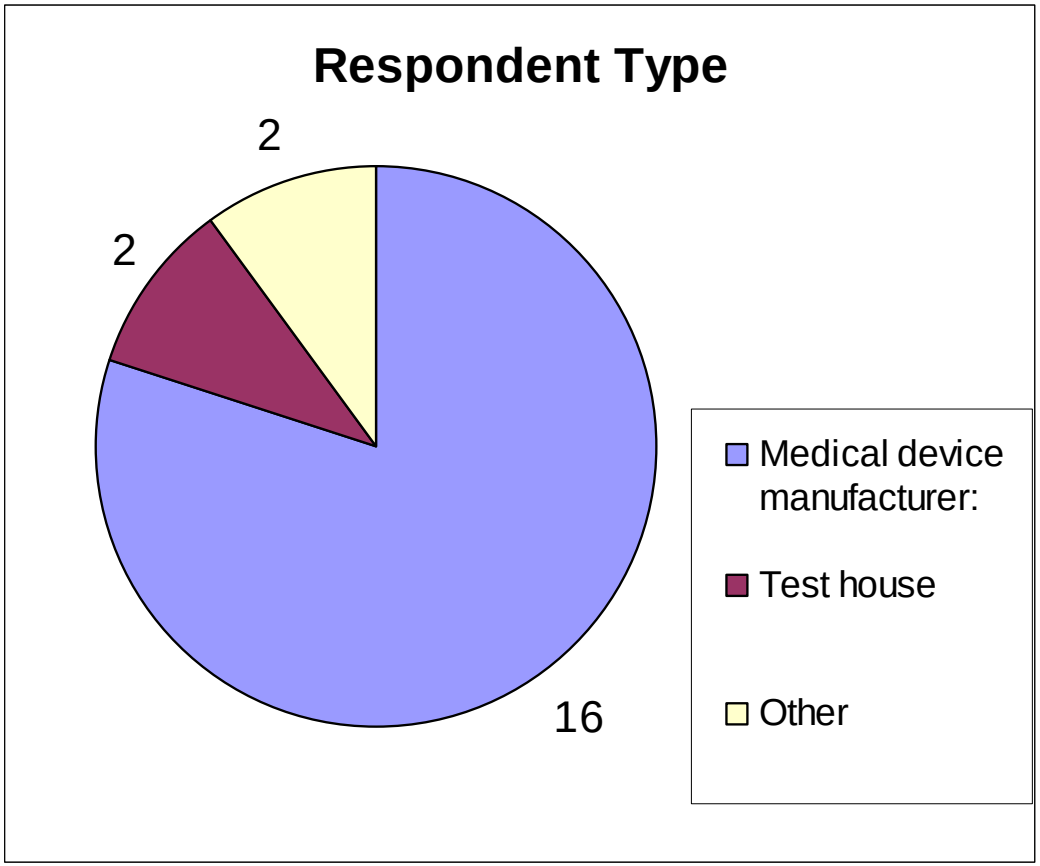
- Nickel Leach and Toxicity
- Summary Session: Potential Testing Paradigms

Workshop Objectives

To provide a forum for the discussion of:

- Methods for corrosion assessments, surface characterization techniques, and nickel leach testing used to evaluate the suitability of metallic cardiovascular implant devices
- Limitations of these tests to predict actual in vivo performance
- Utility/circumstances when these tests should be considered
- Potential testing paradigms, including what could be used as acceptance criteria for each test

Pre-Workshop Homework Respondents



total respondents = 20 (including partial responses)

Note: Standards discussed in the workshop/HW are those commonly used for device characterization; however, other methods may also be appropriate